State of Global Life-Sciences Innovation Policy

Stephen Ezell
VP, Global Innovation Policy
ITIF

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About ITIF

- Independent, nonpartisan research and education institute focusing on intersection of technological innovation and public policy, including:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy

- Mission to formulate and promote policy solutions that accelerate innovation and boost productivity

- Ranked by University of Pennsylvania as top science and technology think tank in United States and number two in world
A Golden Age of Biomedical Innovation

About 7,000 Medicines Under Development Globally

- CANCERS: 836
- HEART DISEASE & STROKE: 190
- ALZHEIMER’S DISEASE: 77
- AUTOIMMUNE DISEASES: 311
- DIABETES: 171
- MENTAL HEALTH DISORDERS: 135
- RARE DISEASES: 566
- NEUROLOGICAL DISORDERS: 420

Source: PhRMA, Chart Pack: Biopharmaceuticals in Perspective, Spring 2017
Developing New-to-the-world Treatments

Percentage of Products in Clinical Development and Regulatory Review That Are Potentially First-in-Class, Selected Therapeutic Areas, 2016

Alzheimer's Disease: 86%
Cancer: 79%
Psychiatry: 75%
Neurology: 74%
Cardiovascular: 73%
Diabetes: 73%
Immunology: 68%
HIV/AIDS: 60%

Source: PhRMA, Chart Pack: Biopharmaceuticals in Perspective, Spring 2017
U.S. Leads in Global Life-Sciences Innovation

U.S. Share of New Active Substances (NAS) Launched First on World Market

Keys to Life-Sciences Innovation Leadership

1. Robust public/private investment in biomedical research.

2. Aggressive incentives to encourage investment. (E.g. R&D tax credit, Orphan Drug Tax Credit)

3. Robust intellectual property protections.

4. Pricing/reimbursement system allowing innovators to earn sufficient revenues.

5. Effective regulatory/drug approval system.

Image of a CAR-T cell (reddish) attacking a leukemia cell (green).
The Global Political Economy of Life-Sciences Innovation

   - Assert that biopharma companies charge too much for drugs.
   - Want government to take leading role in drug development.
   - Advocate for price controls, weaker patent protections, and shorter data-exclusivity periods.

   - Assert that government investment in scientific research is inefficient and wasteful.
   - Want to limit government-supported life-sciences research in order to shrink government and redistribute $$ to taxpayers.
   - Think private sector would invest enough in basic research.
Reasonable Prices Are Vital for Life-Sciences Innovation

- OECD: “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”
- A statistically significant relationship exists between a biopharma enterprise’s profits from the previous year and its R&D expenditures in the current year.

Source: OECD, *Pharmaceutical Pricing Policies in a Global Market*
Reasonable Prices Are Vital for Life-Sciences Innovation

1. Vernon estimates a policy which would regulate U.S. prices in a way equivalent to the rest of the world would result in a decline in firms’ R&D expenditures in the range of 23-33%.

2. Civan estimates a 50% drop in U.S. drug prices would result in the number of drugs in the development pipeline dropping up to 24%.

Source: Golec and Vernon, Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms
Leadership in Biotechnological Innovation Requires Robust IP Protection

Source: Global Intellectual Property Center, IP-A Global Navigation Center for the Knowledge Economy
Factors Affecting Drug Launch in Countries

- New study of 642 new drug launches in 76 countries from 1983 to 2002.
- Finds speed/extent of diffusion strongly associated with countries’ patent and price regulation schemes.
- Moving from a regime of no product patents to long product-patent terms reduces drug launch lags by 55%.

Factors Affecting Drug Launch in Countries

- Countries adopting strong price controls experience “significantly longer lags.”

- Introducing price controls increases drug launch lags 25-80%.

Source: Cockburn, Lanjouw, and Schankerman, *Patents and The Global Diffusion of New Drugs*
Patents and Drug Prices

- Duggal et al. assessed 6,000+ products consisting of 1,000+ molecules in India.
- Estimates molecules receiving a patent saw an average price increase of just 3–6 percent.

“Our results demonstrate that the implementation of product patents for India did not cause either the large increases in pharmaceutical prices or the dramatic consolidation of the market that some predicted prior to its enactment.”

Source: Duggan, Grathwaite, and Goyal, The Market Impacts of Pharmaceutical Product Patents in Developing Countries: Evidence from India
Regulatory Policy Significantly Affects Drug Launches

Number of 2010-2014 Cancer Medicines That Have Been Launched in Various Regions

Source: IMS Institute for Healthcare Informatics, Global

Source: Frank Lichtenberg, "The impact of pharmaceutical innovation on cancer mortality in Mexico, 1998-2014" (Presentation, Mexico City, Mexico, March 30, 2017)
How Developing Countries Fare in Life-Sciences Innovation

Laggards Embrace Compulsion, Not Attraction, Strategies

Source:Courtesy Meir Pugatch, The Pugatch Consilium
Pharmaceutical innovation accounted for 73% of the 2000-2009 increase in life expectancy at birth in 30 countries (1.27 years of the 1.73 year increase).

Note: size of bubble is proportional to country population.

Why Life-Sciences Innovation Matters

- Helping citizens live longer, healthier lives generates economic benefits.
  - Improvement in U.S. life expectancy from 1970 to 1990 added $2.8 trillion to U.S. productivity.
  - This equaled $12,000 per U.S. citizen, per added year of life expectancy.

- Opportunity cost of missing work (especially for chronic diseases)
  - Keeps many out of work, lowers productivity, contributes to absenteeism

- Eliminating heart disease valued at $48 trillion, curing cancer $47 trillion; Alzheimer’s disease will cost $1 trillion a year by 2050.
Investment in Life-Sciences Innovation Pays

Impact of pharmaceutical innovation on per capita drug expenditure, work-loss days, and inpatient expenditure, USA, 2010

- $171 new drug expenditure
- $44 old drug expenditure
- $131 value of reduction in missed workdays
- $366 inpatient expenditure

“The value of reductions in work loss days and hospital admissions attributable to pharmaceutical innovation was three times larger than the cost of new drugs consumed.”

Innovate4Health Initiative – ITIF and CPIP

https://medium.com/innovate4health
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Thank You!

Stephen Ezell  I  sezell@itif.org  I  202.465.2984